K091862

510(k) Summary

14-Sep-2009

PharmaCaribe
1600 Mill Quarter Rd
Powhatan, VA 23139

Tel (804) 339-4523
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NOV 20 2009

Official Contact: Werner Gutmann COO

Proprietary or Trade Name: NESSI Spacer

Common/Usual Name: Spacer / Holding Chamber

Classification Name: Holding Chambers, Direct Patient Interface
NVO - CFR 868.5630

Predicate Devices: K010680 – CT Spacer
K070674 – Trudell AeroChamber Plus

Device Description:
The NESSI is a spacer intended for use in the inhalation of MDIs for the therapy of the upper and lower respiratory system. The device consists of a translucent housing a back piece and mouth piece.

The NESSI Spacer can be used to inhale aerosolized drugs of approved MDIs from the following groups of active substances:

- Corticosteroids (anti-inflammatory medications)
- Anti-cholinergics and β2-sympathomimetics (bronchodilater medications)
- Non-steroidal chromones (DNCG)

It is a single patient, multi-use device.

Indications for Use:
The NESSI Spacer is intended to be used by patients who are under the care of treatment of a licensed healthcare professional or physician. The device is intended to be used by these patients to administer aerosolized medication from pressurized Metered-Dose Inhalers, prescribed by a physician or healthcare professional

Patient Population: Any individual

Environment of Use: Home care, nursing homes, sub-acute institutions, and hospitals

Contraindications: None

Attribute	K010680 Clinical Technologies CT Spacer	K070674 Trudell Medical AeroChamber Plus	Proposed PharmaCaribe NESSI
Indications for Use	The CT Spacer is a spacer used with a MDI or a nebulizer to deliver inhalable drug aerosols to a patient. The spacer is to be used by a single patient, for a maximum of 28 days.	The AeroChamber Plus® a VHC with Flow-Vu® IFI is intended to be used by patients who are under the care or treatment of a licensed health care provider or physician. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, prescribed by a physician or health care professional. The intended environments for use include the home, hospitals and clinics.	The NESSI Spacer is intended to be used by patients who are under the care of treatment of a licensed healthcare professional or physician. The device is intended to be used by these patients to administer aerosolized medication from pressurized Metered-Dose Inhalers, prescribed by a physician or healthcare professional
Environments of use	Not specified	Home, hospitals and clinics.	Home care, nursing homes, sub-acute institutions, and hospitals
Prescriptive	Yes	Yes	Yes
Patient population	Not specified	All	All
Single patient reusable	Yes	Yes	Yes
Used with mouthpiece or face mask	Yes	Yes	Yes
Used with pressurized metered dose inhalers	Yes	Yes	Yes
Anti-static claim	No	Yes	Yes

The NESSI Spacer is viewed as substantially equivalent to the predicate devices because:

Indications –
Similar to predicates - K010680 – CT Spacer and K070674 – Trudell AeroChamber Plus

Technology –
Similar to predicate – K010680 – CT Spacer

Materials –
The materials used are identical to those used in 510(k) K082092, with the identical exposure characteristics and we have provided ISO 10993 testing as well.

Environment of Use –
Identical to K070674 – Trudell AeroChamber Plus

Patient Population –
Similar to K070674 – Trudell AeroChamber Plus

Differences –

The NESSI Spacer is viewed as substantially equivalent to the following predicate devices – K010680 – CT Spacer and K070674 – Trudell AeroChamber Plus.

There are no significant differences that affect the safety or effectiveness of the intended device when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

PharmaCaribe
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

NOV 2 0 2009

Re: K091862
Trade/Device Name: NESSI Spacer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: NVO
Dated: November 12, 2009
Received: November 16, 2009

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K091862** (To be assigned)

Device Name: **NESSI Spacer**

Indications for Use:

The NESSI Spacer is intended to be used by patients who are under the care of treatment of a licensed healthcare professional or physician. The device is intended to be used by these patients to administer aerosolized medication from pressurized Metered-Dose Inhalers, prescribed by a physician or healthcare professional.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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